

**PATENT APPLICATION**  
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of

Docket No: Q75926

Ryuichi MORISHITA, et al.

Divisional Application of  
Appln. No.: 09/660,522

Group Art Unit: 1636 (prior application)

Confirmation No.: Not yet assigned

Examiner: David A. Lambertson (prior application)

Filed: July 9, 2003

For: MEDICAMENT COMPRISING HGF GENE

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. §§ 1.97 and 1.98**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

One copy of each of the listed documents is submitted herewith, along with a copy of the corresponding Communication from a Foreign Patent Office.

The present Information Disclosure Statement is being filed: (1) No later than three months from the application's filing date for an application other than a continued prosecution application (CPA) under §1.53(d); (2) Before the mailing date of the first Office Action on the merits (whichever is later); or (3) Before the mailing date of the first Office Action after filing a

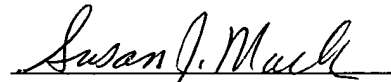
INFORMATION DISCLOSURE STATEMENT

Divisional Application of U.S. Appln. No.: 09/660,522

request for continued examination (RCE) under §1.114, and therefore, no Statement under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

Respectfully submitted,



Susan J. Mack

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WASHINGTON OFFICE



23373

PATENT TRADEMARK OFFICE

Date: July 9, 2003

Substitute for Form 1449 A & B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<i>Complete if Known</i>	
				Application Number	Divisional Application of Appln. No. 09/660,522
				Confirmation Number	Not yet assigned
				Filing Date	July 9, 2003
				First Named Inventor	Ryuichi MORISHITA
				Art Unit	1636 (prior application)
				Examiner Name	David A. Lambertson (prior application)
Sheet	1	of	1	Attorney Docket Number	Q75926

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number	Kind Code <sup>2</sup> (if known)		
		US			
		US			
		US			
		US			
		US			
		US			
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		US			

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Translation <sup>6</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			
	✓	EP	0 461 560	A1	12/18/91	Toshikazu Nakamura	NA
	✓	WO	96/40062		12/19/96	Georgetown University	NA

OTHER ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation <sup>6</sup>

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kind Codes of USPTO Patent Documents at www.uspto.gov, MPEP 901.04 or in the comment box of this document. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to indicate here if English language Translation is attached.

Substitute for Form 1449 A & B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<i>Complete if Known</i>	
				Application Number	Divisional Application of Appln No. 09/660,522
				Confirmation Number	Not yet assigned
				Filing Date	June 9, 2003
				First Named Inventor	Ryuichi MORISHITA
				Art Unit	1636 (prior application)
				Examiner Name	D. Lambertson (prior application)
Sheet	1	Of	2	Attorney Docket Number	Q75926

U.S. PATENT DOCUMENTS					
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		Number	Kind Code <sup>2</sup> (if known)		
		US			
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		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation <sup>6</sup>
		December 30, 2002 Office Action issued in corresponding Taiwanese patent application.	No
		ML LIU, et al., "Hepatocyte growth factor inhibits cell proliferation in vivo of rat hepatocellular carcinomas induced by diethylnitrosamine," Carcinogenesis, April 1995, 16(4): 841-3.	Abstract
		Y. MATSUDA, et al., "Hepatocyte growth factor suppresses the onset of liver cirrhosis and abrogates lethal hepatic dysfunction in rats," J. Biochem., September 1995, 118(3): 643-9.	Abstract
		G. SHIOTA, et al., "Inhibitory effect of hepatocyte growth factor on metastasis of hepatocellular carcinoma in transgenic mice," Res Commun Mol Pathol Pharmacol, January 1996, 91(1): 33-9.	Abstract
		G. SHIOTA, et al., "Characterization of double transgenic mice expressing hepatocyte growth factor and transforming growth factor alpha," Res Commun Mol Pathol Pharmacol, October 1995, 90(1): 17-24.	Abstract
		G. SHIOTA, et al., "Hepatocyte growth factor in transgenic mice: effects on hepatocyte growth, liver regeneration and gene expression," Hepatology, April 1994, 19(4): 962-72.	
		G. SHIOTA, et al., "Hepatocyte growth factor inhibits growth of hepatocellular carcinoma cells," Proc Natl Acad Sci USA, January 1992, 89(1): 373-7.	Yes

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kind Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov), MPEP 901.04 or in the comment box of this document. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to indicate here if English language Translation is attached.

Form PTO-1449  
(Rev. 2-32)

U.S. Department of Commerce  
Patent & Trademark Office

INFORMATION DISCLOSURE STATEMENT  
(Use several sheets if necessary)

Attorney Docket: Q75926

Divisional application of Appln. No. 09/660,552

Applicant: Ryuichi MORISHITA, et al.

Filing Date: July 9, 2003

Group: 1636 (prior application)

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Sub-Class	Filing Date (if appropriate)
	USPN 5,652,225	7/29/97	Isner et al.			
	USPN 5,756,122	5/26/98	Thierry et al			

FOREIGN PATENT DOCUMENTS

Document	Date	Country	Class	Sub-class	Translation Yes/No
WO 96 40062A	12/19/96	WIPO			
WO 91 06309A	5/16/91	WIPO			
EP 0461 560A	12/18/91	EPO			
EP 0494369	7/15/92	EPO			
EP 0492614	7/1/92	EPO			
WO 93/08821	5/13/93	WIPO			
WO 94/06456	3/31/94	WIPO			
WO 92/05184	4/2/92	WIPO			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Nakamura et al., "MOLECULAR CLONING AND EXPRESSION OF HUMAN HEPATOCYTE GROWTH FACTOR", Nature, Vol. 342, November 23, 1989, pages 440-443, XP000652120
	Miyazawa K. et al., "MOLECULAR CLONING AND SEQUENCE ANALYSIS OF cDNA FOR HUMAN HEPATOCYTE GROWTH FACTOR" Biochemical and Biophysical Research Communications, Vol. 163, No. 2, September 15, 1989, pages 967-973, XP000651424
	T. Seki et al., "ISOLATION AND EXPRESSION OF cDNA FOR DIFFERENT FORMS OF HEPATOCYTE GROWTH FACTOR FROM HUMAN LEUKOCYTE" Biochemical and Biophysical Research Communications Vol 172, No. 1, October 15, 1990, pages 321-327, XP002084490
	Japan Financial News Paper (December 14, 1998 w/ English language translation)
	Local News Section of Japan Financial News Paper (December 14, 1998 w/ English language translation)
	Asahi News Paper (November 2, 1999 w/ English language translation)
	Supplement to Circulation Vol. 96, Abstract No. 3459 (October 21, 1997)
	Ueki et al., Nature Medicine 5:226230, 1999
	Research report from the Welfare Ministry Specific Diseases, Pervaded Lung Diseases Sub-group (1997 w/ English language translation)
	Ueda, et al., Ann. Thorac. Surg. 67:1726-1731, 1999
	Preprint of article by Taniyama et al., entitled "Therapeutic Angiogenesis Induced by Human Hepatocyte

# INFORMATION DISCLOSURE STATEMENT

Continuation of U.S. Appln. No.

	(continued from the last page) Growth Factor Gene in Rat and Rabbit Hind Limb Ischemia Models: Pre-clinical Study to Treat Peripheral Arterial Disease."
	Preprint of article by Aoki, et al., entitled "Angiogenesis Induced by Hepatocyte Growth Factor in Non-infarcted Myocardium and Infarcted Myocardium: Up-regulation of Essential Transcription Factor for Angiogenesis, Ets."
	"Scatter Factor (Hepatocyte Growth Factor) is a Potent Angiogenesis Factor IN Vitro" by Rosen et al., Society of Experimental Biology, 1993, pp 227-234
	"Scatter Factor Induces Blood Vessel Formation IN VIVO" by Grant, et al., Proc. Nat'l. Acad. Sci USA, Vol. 90, March 1993, pp 1937-1941
	"Hepatocyte Growth Factor/Scatter Factor Modulates Cell Motility, Proliferation, and Proteoglycan Synthesis of Chondrocytes" by Takebayashi et al., Journal of Cell Biology, Vol. 29, No. 5 1995, pp 1411-1419
	"The Interaction of HGF-SF with other Cytokines in Tumor Invasion and Angiogenesis" by Rosen et al., Vol. 65, 1993, pp. 301-310
	Circulation 96, No. 8, October 21, 1997, No. 3459
	Nature Medicine 5:226-230 (February, 1999)
	Nature 338:557-562, 1989
	Science 235:442-447, 1987
	J. Clin. Invest. 93:662-670, 1993
	J. Vasc. Surg. 16:181-191, 1998
	Circulation 97:645-650, 1998
	Circulation 98:2800-2804, 1998
	J. Bone & Joint Surg. 71:74-80, 1989
	New England J. Medicine 331:889-895, 1994
	Gut, Supplement No. 5, Vol. 35, s-60, F240 (1994)
	Biochem and Biophys Res. Comm. 220, 539-545 (1996), Hayashi et al., "Autocrine-paracrine effects of overexpression of hepatocyte growth factor gene on growth of endothelial cells
	Verma et al., "Gene therapy promises, problems and prospects," Nature 389:239-242 (1997)
	Morishita, et al., "Novel in vitro gene transfer method for study of local modulators in vascular smooth muscle cells," Hypertension 21:894-899 (1993)
EXAMINER:	DATE CONSIDERED:
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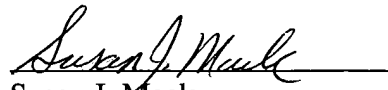
In accordance with the duty of disclosure under 37 CFR §1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form which are all the references of record in parent applications No. 09/660,522 and 09/029,497. Applicant is not submitting duplicate copies of these references but requests that they be listed on the face of any patent granted on the above application. (See 37 CFR §1.98(d)). Copies of any cited copending applications, if not previously submitted, are being submitted herewith.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not

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Respectfully submitted,

  
Susan J. Mack  
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WASHINGTON OFFICE



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P.O. Box 1450  
Alexandria, VA 22313-1450

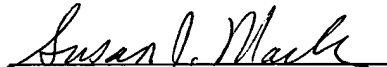
Sir:

The undersigned hereby states, upon information and belief:

That each item of information contained in the Information Disclosure Statement filed concurrently herewith was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of said Information Disclosure Statement.

Respectfully submitted,

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